

Message

From: Toxicology Forum Headquarters [Info@toxforum.org]
Sent: 1/7/2015 7:18:17 PM
To: cportier@mac.com; Cogliano, Vincent [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51f2736376ac4d32bad2fe7cfef2886b-Cogliano, Vincent]; jbus@exponent.com; 'goncalo.gamboa@fda.hhs.gov' [goncalo.gamboa@fda.hhs.gov]
CC: gary.d.minsavage@exxonmobil.com
Subject: RE: ToxForum Session - Actions and Alignment

Importance: High

Dear All,

This is just a reminder about the message below. If you could please respond to the Doodle Poll linked to below today or first thing tomorrow morning that would be much appreciated. Some of the dates/times will have already passed.

Thank you in advance.

Doodle Poll: <http://doodle.com/82u9gwkw8dzrcns5>

Kevin Merritt
The Toxicology Forum
1821 Michael Faraday Drive
Suite 300
Reston, VA 20190
P: 703.547.0876
Email: info@toxforum.org

-----Original Message-----

From: "Toxicology Forum Headquarters" <Info@toxforum.org>
To: "cportier@mac.com" <cportier@mac.com>, "cogliano.vincent@epa.gov" <cogliano.vincent@epa.gov>, "schoeny.rita@epa.gov" <schoeny.rita@epa.gov>, "jbus@exponent.com" <jbus@exponent.com>, "goncalo.gamboa@fda.hhs.gov" <goncalo.gamboa@fda.hhs.gov>
Date: Tue, 23 Dec 2014 17:14:57 -0500
Subject: RE: ToxForum Session - Actions and Alignment

Dear All,

Below you will find a link to the requested Doodle Poll. Please be sure to respond at your earliest convenience and to expand the possible date/time options by clicking between the initial polling dates. Please note that all times in the poll are Eastern Standard Time. You are welcome to contact me if you have any concerns.

Doodle Poll: <http://doodle.com/82u9gwkw8dzrcns5>

Happy Holidays!

Regards,

Kevin Merritt
The Toxicology Forum
1821 Michael Faraday Drive
Suite 300
Reston, VA 20190
P: 703.547.0876

Email: info@toxforum.org

From: Minsavage, Gary D [mailto:gary.d.minsavage@exxonmobil.com]
Sent: Tuesday, December 23, 2014 4:50 PM
To: cportier@mac.com; cogliano.vincent@epa.gov; Schoeny, Rita; James Bus; Gamboa, Goncalo
Cc: Kevin Merritt (kevin@toxicology.org); tmasson@toxforum.org
Subject: RE: ToxForum Session - Actions and Alignment

Dear Drs. Bus, Cogliano, Gamboa da Costa, Portier and Schoeny

First, I'd like to wish you very Happy Holidays, and all the best wishes for you in the New Year.

Second, I am sending this email as a very brief status update for your information.

I realize this time of year has been, as expected, difficult to get us all coordinated, but thank you for those that could find the time to provide specific titles (updates for titles I've been provided are below) and exchanged a few emails with me to start to get aligned.

The ToxForum Offices will send an email to all of you with a doodle poll for the first part of January (dates including Jan 5-13). Please provide your availability for a 1 hour call to get aligned for the January ToxForum Winter Session.

Looking forward to a great ToxForum Winter Meeting. Thank you again, in advance, for your time and energy on this session. We'll be in touch soon.

Happy Holidays!

Gary D. Minsavage, Ph.D., DABT
ToxForum Winter Planning Committee Representative

Contact information:
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From: Minsavage, Gary D
Sent: Wednesday, November 19, 2014 11:08 AM
Subject: ToxForum Session - Actions and Alignment

Dear Drs. Bus, Cogliano, Gamboa da Costa, Portier and Schoeny:

On behalf of the Planning Committee for the 39th Annual Winter Toxicology Forum I wanted to again thank you for accepting the invitation to present at the Forum regarding standardization of criteria and approach to use of mechanistic/mode of action data in cancer classification decision making.

May I please ask you to take note of and reply to the following actions/requests -

- 1) **REPLY TO FORMAL INVITATION:** By now, the Toxicology Forum Office has been in touch with you with a formal invitation. Please reply to the Office as soon as possible, if you've not already done so. Thank you.

- 2) **REVIEW AGENDA:** see below for your session details with full agenda available at [ToxForum 39th Annual Winter Meeting](#).
- 3) **PREPARE FOR SESSION:** I'd like to propose that the speakers and session chair work to fully align on focus/intent of the session, minimize overlap of background information across presentations, and maximize sharing information in presentations that drives dialogue across presenters and with the audience. A goal of ToxForum is to build better understanding through dialogue. You are each preparing a 20 minute presentation that will be followed by a 10 minute Q&A session aimed at your presentation. There will be a 30 minute panel discussion at the end of the session in which all of the speakers/chair will participate.
- a. **EXCHANGE OF INFORMATION BY SPEAKERS:** Toward this end, I'd be happy to arrange a (series of) conference calls. At a minimum, particularly with holidays approaching, I'd propose email exchanges with this full group may help get everyone aligned.
 - i. **INITIAL THOUGHTS / QUESTIONS:** if you've got burning questions or ideas on the content and/or flow of this session, please email them to the group.
 - ii. **CALL NEXT WEEK?** Please let me know if you are available for a call in the afternoon of 24 Nov ("kick-off call") and if so, what timeslots are available for you? If not, please offer blocks of time that may work through Dec 5th
 - b. **PROPOSED TIMELINE (for your consideration):**

	i. "Kick-off email exchange/call":	by Dec 5th
	ii. FIRST DRAFT SLIDES:	December
20 th		
	iii. Alignment email/call:	week of
January 6 th or early week of 13th		
	iv. FINAL DRAFT SLIDES:	January
10th		
	v. FINAL SLIDES:	January
17th		

Thank you, again. Please do not hesitate to contact me with any questions.

Session Details (also found on ToxForum Website):

MEETING LOCATION AND DATES

January 26-28, 2015

The Fairfax at Embassy Row Hotel, Washington, DC

SESSION TOPIC

Debating the Varying Criteria for Incorporating "Mechanistic Data" into Cancer Classification

BACKGROUND TO PROPOSED SESSION

As you are likely aware, IARC recently published a report "IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: [Report](#) of the Advisory Group to Recommend Priorities for IARC Monographs during 2015-2019". It is understood that the Advisory Group was asked to consider prospects for the evaluation of mechanistic data in the context of Monograph evaluations. A key element of the recommendation is to understand the criteria for utilizing "mechanistic data/mode of action" in classification decision making. In addition, other organizations consider how to utilize mode of action / mechanistic data to guide decisions on cancer hazard assessments. This ToxForum session will allow for discussion about the approaches various organizations take or are considering taking in the future; criteria and standards of acceptance and specifically what and how such information is needed for decision making will be discussed.

SESSION TIME

Wednesday, January 28, 1:30 p.m. – 5:00 p.m. EDT

FINAL SPEAKERS AND TIMESLOTS

1:30-1:50 (+10 minute Q&A)

Jim Bus

Toxicology and Mechanistic Biology, Exponent

Session introduction and overview of the issues and opportunities

2:00- 2:20 (+10 minute Q&A)

Christopher Portier

Title: Mechanistic Data, Cellular Pathways and Cancer Classification

Title provided by Dr. Portier: *Mechanistic Data, Cellular Pathways and Cancer Classification*

2:30-2:50 (+10 minute Q&A)

Gonçalo Gamboa da Costa

FDA NCTR

Title provided by Dr. Gamboa da Costa: *NCTR perspective on the incorporation of mechanistic data in cancer studies*

3:00-3:30 break

3:30 -3:50 (+10 minute Q&A)

Rita Schoeny

EPA ORD

Perspectives from EPA ORD regarding standardization of criteria and approach to use of mechanistic/mode of action data in cancer classification decision making

4:00-4:20 (+10 minute Q&A)

Vincent Cogliano

NCEA - EPA IRIS

Perspectives from EPA IRIS regarding standardization of criteria and approach to use of mechanistic/mode of action data in cancer classification decision making

4:30 – 5:00

Panel Discussion: Panel Members will include Chair, Invited Speakers, and others

Kind regards,
Gary

Gary D. Minsavage, Ph.D., DABT
ToxForum Winter Planning Committee Representative

Contact information:

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